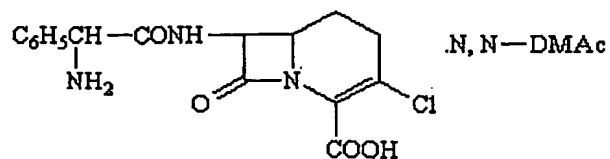


We Claim:

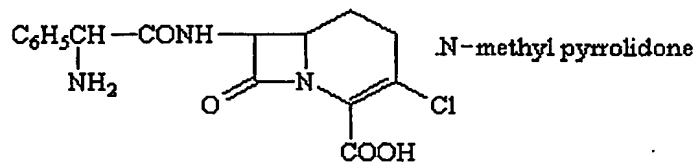
1. Mono N,N-Dimethylacetamide monohydrate solvate of loracarbef of
Formula II-A.

**FORMULA - II - A**

2. The compound of claim 1 which has the following X-ray diffraction powder
pattern:

d	I/I ₀
15.6	17.0
11.80	100
11.12	41
7.43	25
5.91	12
5.19	14
4.88	16
4.76	22
4.69	17
4.45	13
4.28	13
3.93	70
3.639	28
3.33	18
3.177	71
2.949	18
2.729	13
2.6122	13

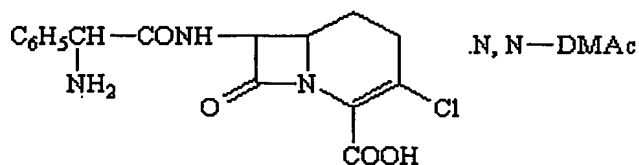
3. Mono N-Methylpyrrolidone monohydrate solvate of loracarbef of Formula II-B.

**FORMULA - II - B**

- 1 4. The compound of claim 3 which has the following X-ray diffraction powder
2 pattern:

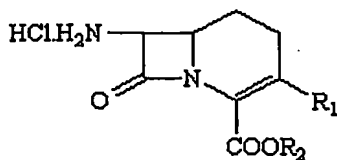
d	I/I ₀
15.8248	14
15.2251	13
12.0338	100
8.0954	8
7.5189	33
5.9968	13
5.4668	12
5.3810	14
5.2605	18
4.8863	22
4.7513	37
4.4579	21
4.2997	22
4.1411	16
3.9939	55
3.6421	38
3.3858	18
2.7314	15

- 1 5. A process for the preparation of mono-N, N-dimethylacetamide monohydrate
2 solvate of loracarbef of Formula II-A,



6 **FORMULA - II-A**

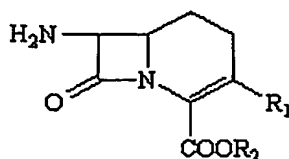
7 comprising mixing a compound of Formula III,



11 **FORMULA - III**

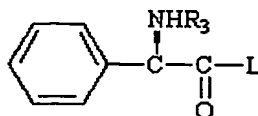
12 wherein R₁ is hydrogen, trihalo (C₁-C₄ alkyl), C₁-C₄ alkyl, C₁-C₄ substituted alkyl,
13 C₁-C₄ alkoxy, C₁-C₄ substituted alkoxy, C₁-C₆ alkylthio, C₁-C₆ substituted
14 alkylthio, methoxy methyl, carbamoyloxy methyl, acetoxymethyl, C₂-C₆ alkenyl,

C₂-C₆ substituted alkenyl, or halogen such as bromo, chloro, fluoro, and iodo; and R₂ is a carboxy-protecting group, with N,N-dimethylacetamide and a base to form a free amine of the compound of formula IV, and



FORMULA - IV

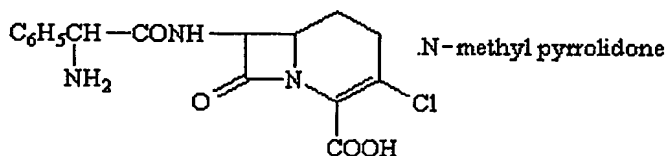
reacting the compound of Formula IV with an acylating agent of Formula V,



FORMULA V

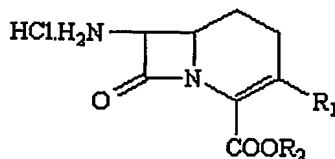
wherein R₃ is an amino protecting group and L is a leaving group.

6. A process for the preparation of mono N-methylpyrrolidone monohydrate solvate of loracarbef of Formula II-B,



FORMULA - II-B

comprising mixing a compound of Formula III,

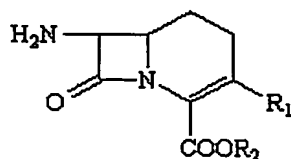


FORMULA - III

wherein R₁ is hydrogen, trihalo (C₁-C₄ alkyl), C₁-C₄ alkyl, C₁-C₄ substituted alkyl, C₁-C₄ alkoxy, C₁-C₄ substituted alkoxy, C₁-C₆ alkylthio, C₁-C₆ substituted alkylthio, methoxy methyl, carbamoyloxy methyl, acetoxymethyl, C₂-C₆ alkenyl,

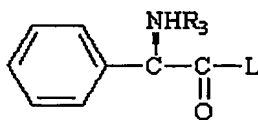
C₂-C₆ substituted alkenyl, or halogen such as bromo, chloro, fluoro, and iodo; and R₂ is a carboxy-protecting group,

with N-methylpyrrolidone and a base, to form a free amine of the compound of formula IV, and



FORMULA - IV

reacting the compound of Formula IV with an acylating agent of Formula V,



FORMULA V

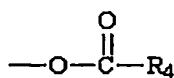
wherein R₃ is an amino protecting group and L is a leaving group.

7. The process according to claim 5 or 6, wherein the carboxyl protecting group, R₂ is selected from the group consisting of allyl, alkyl, benzyl, substituted benzyl, silyl, halo-substituted alkyl and alkoxyalkyl.

8. The process according to claim 7, wherein the carboxyl protecting group is 4-nitrobenzyl.

9. The process according to claim 5 or 6, wherein the amino-protecting group, R₃ is selected from the group consisting of alkoxy-carbonyl, phenoxy-carbonyl, phenoxy-acyl, alkoxy-acyl, aralkoxy-carbonyl, enamino derived from C₁₋₄ alkylacetoacetate and acyl.

10. The process according to claim 5 or 6, wherein the leaving group L is compound of Formula VI,



FORMULA VI

- 6 wherein R₄ is selected from the group consisting of halo such as chloro, bromo,
7 iodo or C₁₋₆ alkyl, benzyl, substituted benzyl, phenyl, substituted phenyl, adducts
8 of dicyclohexylcarbodiimide and alkoxyalkyl.
- 1 11. The process according to claim 5 or 6, wherein the base is a cyclic amine base
2 containing 0-1 oxygen atom.
- 1 12. The process according to claim 11, wherein the cyclic amine base is selected from
2 the group consisting of five- or six- membered tertiary cyclic amines.
- 1 13. The process of claim 12, wherein the cyclic amine base is N-methylmorpholine or
2 N-methylpiperazine.
- 1 14. A process for the preparation of crystalline monohydrate of loracarbef, the process
2 comprising:
3 treating mono N,N-dimethylacetamide monohydrate solvate of loracarbef with an
4 acid, and
5 adjusting the pH with a base to afford the crystalline monohydrate of loracarbef.
- 1 15. A process for the preparation of crystalline monohydrate of loracarbef, the process
2 comprising:
3 treating mono N-methylpyrrolidone monohydrate solvate of loracarbef with an
4 acid, and
5 adjusting the pH with a base to afford the crystalline monohydrate of loracarbef.
- 1 16. The process according to claim 14 or 15, wherein the acid used is a mineral acid
2 or an organic acid.
- 1 17. The process according to claim 16, wherein the acid is hydrochloric acid.
- 1 18. The process according to claim 14 or 15, wherein the base used is ammonia.
- 1 19. Crystalline monohydrate of loracarbef having a bulk density greater than or equal
2 to 0.6 g/ml.
- 1 20. A pharmaceutical composition comprising:
2 a therapeutically effective amount of a crystalline monohydrate of loracarbef
3 having a bulk density greater than or equal to 0.6 g/ml;
4 and one or more pharmaceutically acceptable carriers, excipients or diluents.